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A SEMIAUTOMATIC DEVICE FOR SUTURING WITH SURGICAL THREAD

The present invention relates to a semiautomatic implantable surgical device for suturing with surgical thread. More particularly, the present invention relates to a suture device including blocking means for blocking together two strands of thread in a suture.

The present invention relates still more particularly to a device for suturing by a minimally invasive surgical approach. Minimally invasive surgery consists in making cutaneous and parietal incisions of small size and introducing instruments and viewing means such as a camera in order to perform an operation in video-assisted manner through orifices having a diameter lying in the range 3 millimeters (mm) to 12 mm by means of a hollow cylindrical instrument referred to as a "trocar".

BACKGROUND OF THE INVENTION

In minimally invasive surgery, anastomoses are often made using sutures of surgical thread secured by knots. Tying a knot on an organ or a vessel constitutes a difficult step during surgery since:

- any slackening of sutures can lead to complications that are severe or even fatal;
- tying knots while using a laparoscopic approach is technically difficult; and
- the increasing number of knots required increases the duration of surgery in significant manner, and for certain operations, such as those involving vascular clamping where operating time must be kept very short, that can run the risk of leading to operative or post-operative complications.

Proposals have been made to use clip or staple type devices, in particular in US patent No. 5 356 459 which seeks to replace suture thread in order to avoid the need to tie knots. Nevertheless, surgeons prefer to use thread when suturing, since they have acquired automatic and habitual skills such that the sutures they make in

this way are tried and tested. In addition, the reliability of clip or staple type devices has yet to be validated.

OBJECTS AND SUMMARY OF THE INVENTION

That is why the present invention seeks to provide a device for suturing using a thread, but offering an alternative to tying knots so as to make it easier to connect two strands of suture thread together, and making it possible significantly to reduce the time required for connecting said strands of thread together.

The inventors have discovered that one of the difficulties in tying knots in suture thread lies in the need for the surgeon to exert tension on the thread, firstly in order to tighten the suture prior to making a permanent connection between the two strands of thread, and secondly to make it easier to tie the knot. One difficulty thus lies in the need for the surgeon to control the tension to be exerted on the thread in order to avoid tightening excessively, or conversely tightening insufficiently, which in both cases would lead to a suture that is ineffective. Controlling thread tension and tying the knots themselves are both acts that are difficult since they need to be done using forceps that are long (20 centimeters (cm) to 30 cm), through trocars, and in a space that is confined. Excessively tightening the threads can lead to a thread itself breaking or to pinching of the biological tissue that is to be repaired. Such pinching can lead to phenomena of tissue rupture or of inflammatory reaction. In contrast, when tightening is not sufficient, the junction between pieces of tissue or between a tissue and a prosthesis can be imperfect and the suture is not leaktight.

US patents Nos. 5 669 917, 6 066 160, 6 077 277, 6 217 591, and 6 293 961 propose various devices enabling two strands of thread to be connected and blocked together instead of requiring the surgeon to tie knots. Nevertheless, in those prior devices, it is always

necessary to put the thread under tension in order to tighten the suture before connecting and blocking together the two strands of thread. During this step, it is not possible for the tension exerted on the thread by the surgeon to be controlled automatically in any way.

In addition, in some of the proposed devices, the suture that is made cannot be easily undone, should that be necessary.

The object of the present invention is thus to provide a surgical suture device that is compatible with using conventional suture thread so as to conserve the benefits of conventional surgery and increase the confidence of the surgeon, while remedying the drawbacks of prior devices.

In particular, an object of the present invention is to provide a suture device that makes it possible to block suture threads quickly and reliably in a manner that is semiautomatic for the surgeon.

Another object of the present invention is to provide a suture device such that the suture made thereby is of reversible or removable character, and in particular can be cut almost instantaneously without any risk of damaging the surrounding tissues.

For this purpose, the present invention provides a suture device comprising: blocking means for connecting together two strands of thread in a blocking zone; and controlled tensioning means for controlled tensioning of said thread, and suitable, after the two strands of said thread have been blocked together using said blocking means, for exerting tension on the thread at a first predetermined tension value.

More precisely, the present invention provides an implantable device for semiautomatic suturing using a surgical thread, the suturing enabling biological and/or artificial tissues to be united, the device comprising: blocking means enabling two strands of the thread of a suture to be connected together in a blocking zone; a

bearing element having a bearing surface for bearing against the tissues to be sutured together; and controlled tensioning means for applying controlled tensioning to said thread, and suitable, after the two strands of said thread have been blocked together using said blocking means, for exerting a tension at a first predetermined tension value, with the junction between said bearing element and said blocking zone of the device being provided by said controlled tensioning means.

Two strands of thread are said herein to be "connected together" when the two strands cannot move relative to each other in said blocking zone, i.e. they are not necessarily in contact with each other in said blocking zone.

The device can be used to unite pieces of biological tissue, one or more pieces of biological tissue with one or more pieces of artificial tissue, or solely pieces of artificial tissue.

In the device of the invention, said blocking means and said tensioning means are suitable for co-operating so that two strands of suture thread are blocked together before exerting said first predetermined tension value, and once the two strands have been blocked together, the device tensions the suture threads at said first predetermined tension value in automatic manner.

Tensioning said suture thread enables the two pieces of tissue, or a piece of tissue and a prosthesis, that are to be united by said suture to be moved together effectively by tightening the thread. With prostheses, said tissue can be biological or artificial.

The term "controlled tensioning" is used herein to mean tensioning at a said first known and predetermined tension value, which tensioning can be applied automatically using said tensioning means, and no longer depends on the initial tension exerted manually by the surgeon on the thread or on a device; that is why the device of the invention is said to be "semiautomatic".

The fact of tensioning the suture threads to a said first predetermined tension value in controlled manner gives the device dynamometric behavior and contributes to the effectiveness of the device and the speed and ease of suturing using the device. The dynamometric behavior of the device of the invention serves to ensure that tensioning is applied appropriately, uniformly, reliably, and repetitively on the threads that are to constitute the suture. Having tension that is uniform makes it possible to distribute forces evenly over the sutured tissues, and thus to minimize aggression to said tissues.

Said first predetermined tension value may preferably lie in the range 0.1 newtons (N) to 10 N, depending on the site of surgery, i.e. depending on the type of tissue to be sutured and depending on the type of suture thread used, and in particular it may be about 2 N which corresponds to the mean tension value of a suture made between a vessel and a vascular prosthesis during conventional surgery under good operating conditions.

In a preferred embodiment, the blocking of said strands of thread using said blocking means is suitable for automatically triggering said tensioning of the thread at a said first predetermined tension value, preferably lying in the range 0.1 N to 10 N.

More particularly, in a dynamometric suture device of the invention, said controlled tensioning means are suitable for co-operating with:

· a bearing element having a bearing surface for bearing against said tissue to be sutured in a zone (4_1) where the device contacts said tissue; preferably in the proximity of suture orifices in said tissue; and

· said blocking means (2) in such a manner as to enable the distance between said blocking zone and said zone of contact between the device and the tissue to be adjusted between:

· an initial distance (L) in which said blocking of the two ends of the strands of thread can be

performed with the thread being at a tension that is preferably small; and

· a final distance ($L' = L \pm b$) suitable for exerting a said controlled tension at a said first predetermined tensioning value.

Thus, if the tension exerted by the surgeon on the thread prior to blocking is less than said first predetermined tension value, then said final distance ($L + b$) will be longer than said initial distance, and conversely if the tension exerted on the thread by the surgeon prior to blocking is greater than said predetermined tension, then said final distance ($L - b$) will be shorter than said initial distance.

Still more particularly, in a suture device of the invention, said tensioning means for adjusting the distance between a said zone of contact on said tissue and said blocking zone, comprise said junction means between said contact zone and said blocking zone.

Said first controlled tension value is thus achieved by adjusting the distance between two zones, namely a contact zone and a blocking zone, by means of a junction element, which adjustment is a function both of said initial distance between said two zones and of the initial tension of the thread as exerted by the surgeon prior to blocking.

As mentioned above, tensioning the threads, and thus implementing said adjusted distance between the contact zone and the blocking zone, is preferably triggered automatically by causing said thread blocking means to operate. Nevertheless, such triggering can be implemented manually by the operator, particularly by relaxing a pressure being exerted by the operator for maintaining said initial pressure manually.

The device of the invention is advantageously put into contact with the tissue to be sutured by means of a placing instrument known as an "ancillary". The suture device of the invention is thus suitable for co-operating

with said placing instrument to which it is secured prior to said blocking, preferably being secured via a top portion corresponding to said blocking zone, and, where appropriate, tensioning of the thread after blocking may be triggered manually using said placing instrument.

In an embodiment, the placing instrument may also serve to cut the ends of the strands of suture thread over the thread blocking zone at a distance lying in the range 1 mm to 10 mm, and in particular 5 mm to 6 mm from the blocking zone, after the threads have been blocked together and depending on the anatomatic site of the surgery.

In a preferred embodiment, said tensioning means comprise means for establishing a resilient junction between said contact zone and said blocking zone so as to enable the distance to be adjusted between:

· a controlled initial distance (L) in which the spacing between said contact zone and said blocking zone is controlled by a first link element or a first spacer element, with said initial distance (L) corresponding to a distance in which said blocking zone and contact zone are in a close position obtained by compression from a remote, rest position (L + a); and

· said final adjusted distance ($L' = L \pm b$, $b < a$) which corresponds to a force equilibrium position in which the distance between said contact zone and said blocking zone is no longer controlled by a said first link element or a said first spacer element.

The term "force equilibrium" is used herein to mean equilibrium between the force exerted by the junction means and the tension of the suture.

Said first link element and/or said first spacer element may be secured to said placing instrument or to said suture device proper.

More particularly, said junction means are made of a material that presents elasticity, and said suture device

is secured to the placing instrument via said blocking zone such that:

· when pressure is exerted on said blocking zone, it is possible, where appropriate, to move said blocking zone from the natural, rest position (L + a) of the device to said initial distance (L), in which said blocking together of the two strands of thread can be implemented under arbitrary tension as exerted on the suture thread by the surgeon, and preferably under no tension; and

· said tensioning of the suture thread exerted by the device of the invention takes place after said blocking by returning said blocking zone to a said adjusted final distance (L ± b) on releasing the pressure exerted on said blocking zone.

The blocking zone and the contact zone can be brought towards each other to said initial distance (L) even before the threads are inserted into the device. The device is then pre-stressed when in position in its placing instrument.

In a first variant embodiment, said initial distance may be obtained using a first link element such as a tab suitable for initially connecting said blocking zone and said tissue contact zone, and said adjusted final distance of said blocking zone relative to said contact zone can be implemented by releasing said first link element connecting together said blocking zone and said contact zone of the device.

Preferably, said first link element forms a part of said suture device of the invention, and release of said link element can be triggered manually, in particular using the instrument for placing the device of the invention, or else it can be triggered automatically, if said first link element is also connected to said blocking means in such a manner as to release first link element once said blocking means have been locked.

That is why, in a preferred embodiment, said first link element is suitable for co-operating with said blocking means so that said first link element is released once said strands of thread have been blocked together with the help of said blocking means.

In a second variant embodiment of the invention, the device includes resilient junction means and it is suitable for co-operating with a placing instrument to which it is preferably secured via a top portion corresponding to said blocking zone, such that:

· prior to said contact zone coming into contact with said tissue, said resilient junction means are at rest and said contact zone and said blocking zone are in the remote position (L + a);

· when said contact zone is caused to exert pressure on said tissue to be sutured, said resilient junction means are in compression and the distance between said blocking zone and said contact zone decreases down to a said initial distance (L) as controlled by a said minimum spacer element, which element is preferably secured to said placing instrument, said bearing contact zone coming into abutment against said spacer element of said placing instrument; and

· said final distance (L ± b, b < a) is obtained by co-operation between said spacing instrument and said device, preferably by separating said placing instrument from said suture device.

The term "resilient junction means at rest" is used to mean that said resilient means are not under stress.

More particularly, said junction means are made of a material that presents elasticity, and the displacement of said blocking zone and said contact zone is controlled by the placing instrument which is secured to said blocking zone in such a manner that:

· when pressure is exerted on said blocking zone, said blocking zone can be moved from a remote position (L + a) to a first close position (L) corresponding to said

initial distance, in abutment against said first spacer element of said placing instrument, in which it is possible to block the two strands of thread together under arbitrary tension exerted by the surgeon, which tension may be greater than or less than said first predetermined tension value; and

· the suture thread is tensioned after said blocking and after the placing instrument has been withdrawn, when the pressure exerted on said blocking zone is released by moving said blocking zone towards a second adjusted position (L ± b), which position may be closer (L - b) than said first position if the tension exerted on the thread by the surgeon was greater than said predetermined tension value, or it may be further away (L + b) than said first position if the tension exerted on the thread by the surgeon was less than said predetermined tension value.

According to another advantageous characteristic of the device of the invention, it is of a shape such that after suturing has been performed, the thread is unencumbered so as to be capable of being cut between said blocking zone and said suture orifices in said tissue, and preferably between said blocking zone and said contact zone.

This makes it easier to cut the threads, and also to eliminate the suture should that be necessary. The reversible nature of the suturing performed by the device makes it possible, in the event of wrong positioning, to return to a preceding situation almost instantaneously, thus giving the surgeon greater freedom of choice and freedom of action throughout the time surgery is taking place.

According to another advantageous characteristic of the device of the invention, it includes guide means enabling the two strands of thread to be held in a position where they are spaced apart from each other laterally at the suture orifices in said tissue.

Said guide means are more particularly suitable for maintaining the two threads in a spaced-apart position when tension is exerted on said thread after the strands of thread have been connected together at said blocking zone by said blocking means. It will be understood that said guide means then make it possible to avoid tearing the tissue at the orifices where the thread passes through said tissue when tension is exerted on the thread after the ends of the thread have been blocked together.

More particularly, the device of the invention has said guide means at said thrust surface defining said zone of contact between the device and the tissue.

In a preferred embodiment of the invention, said guide means comprise at least one notch formed in said bearing surface defining said contact zone.

Also preferably, beneath a said notch, said bearing surface has a piece of fabric made of biocompatible materials and suitable for having two strands of thread pass therethrough, and suitable for keeping them spaced apart. The fabric may be constituted in particular by a synthetic material that facilitates hemostasis and that preserves the integrity of the biological or synthetic tissues to be sutured. In particular, it an be constituted by a piece of vascular prosthesis, a compress, or a swab.

In the conventional technique for maintaining lateral spacing between the orifices in a conventional suture, the surgeon uses a "pledget". This is a piece of fabric, in particular made of Dacron® or Teflon®, through which the surgeon passes the two strands of thread separately, and it acts as an intermediary between the knots and the tissue to be sutured.

In the invention, the covering of biocompatible material acting as means for guiding and separating the strands of the suture thread where they leave the sutured tissues also acts as a traditional pledget, but it is integrated in the device, thereby making contact between

the device and the tissue gentler and less traumatic, and performing the pledget function of facilitating hemostasis and preserving the integrity of the sutured tissues.

In a preferred embodiment, said blocking means comprise two blocking surfaces which can move between a spaced-apart position in which it is possible to insert said strands of suture thread between said two blocking surfaces, and which is suitable for blocking the strands of thread together by friction between the threads and said two blocking surfaces once the surfaces are in the close-together, blocking position, with the displacement of said two blocking surfaces between said spaced-apart position and said close-together position preferably automatically triggering said tensioning of the threads.

It is advantageous for the suture threads to be blocked together by a friction force rather than by a pinching force which would imply a risk of the threads breaking. For this purpose, said blocking surfaces need to present the following characteristics:

· the material used for making the blocking surfaces must be compatible with the material constituting the suture threads;

· the surfaces must be as large as possible in order to maximize contact area with the threads, thereby increasing the friction force; and

· the surfaces must not present sharp angles that might cut the thread.

In a preferred embodiment of the device of the invention, said blocking of the strands of thread using said blocking means is suitable for being triggered automatically.

Automatic triggering of the blocking mechanism can take place via the instrument that is used for inserting and placing the device of the invention at the suture.

More particularly, the automatic triggering of said blocking means can take place when the device of the

invention is put into contact with the tissues for suturing with a bearing force that is greater than a second predetermined value lying in the range 0.2 N to 20 N, and in particular greater than 10 N. This bearing force estimated at 10 N corresponds to the force developed by a surgeon when pulling on the suture threads while making a first knot in a traditional suture for performing anastomosis of the abdominal aorta. The magnitude of this bearing force naturally varies with the type of surgery being performed and with the type of suture thread being used.

Advantageously, said blocking means comprise two jaws that are elastically connected together and that form said blocking surfaces, which jaws are spaced apart by a second spacer element, and said second spacer element is suitable for being released by being disengaged or by being broken, thereby allowing said blocking surfaces to move towards each other and block said strands of thread.

Said second spacer element may be an element of said suture device itself, or of said placing instrument.

More particularly, said second spacer element is suitable for being released automatically, preferably by said placing instrument pressing against said second spacer element, whenever said bearing surface of the device exerts pressure on the tissues that is greater than a said second predetermined value preferably lying in the range 0.2 N to 20 N, and more preferably of at least 10 N.

Still more particularly, said second spacer element is suitable for being released by automatically triggering the release of said first link element between said blocking zone and said contact zone of the device so that said zones adopt said adjusted final distance that enables a said control tension to be exerted on said thread.

In an advantageous embodiment of the present invention, the bearing force exerted at the base of the device of the invention against the tissues enables said second spacer element to be released, thereby preferably triggering tensioning of the thread after said strands of thread have been blocked, tensioning being at a said first tension value, by releasing, where appropriate, said first link element for maintaining the fixed spacing between said blocking zone and said contact zone at said initial distance, so that said blocking and contact zones adopt a said adjusted distance.

In another embodiment, said blocking means comprise projecting elements that are preferably of circular section, more preferably of cylindrical shape, having the ends of the strands of thread for connection together wound thereabout. More particularly, said blocking can be achieved by moving said projecting elements towards each other or away from each other.

In another embodiment, said blocking means include a blocking orifice in said blocking zone, said blocking orifice co-operating with a second blocking element comprising a screw, a rivet, a pushbutton, or indeed a jam cleat.

In another embodiment, said blocking means comprise means for sticking, melting, heat-sealing, or crimping the two strands of thread together in a said blocking zone.

Preferably, the blocking between said strands of thread must be capable of withstanding a traction force lying in the range 0.5 N to 50 N, and in particular of about 20 N to 30 N, with the suture thread breaking at a higher force.

If the shape of the device of the invention, and if particular of said junction element between said bearing surface and said blocking zone, does not make it possible to provide access for cutting the threads in order to undo the suture and remove the device, an alternative is

to provide blocking means in such a manner that the blocking means can be unlocked with an instrument, thereby releasing the threads from being blocked together.

In the present invention, the term "implantable device" is used to mean a device of size and of biocompatible constituent materials that enable it to be implanted in the human body, and more particularly implanted for the long term, inside the human body, i.e. for a duration of more than 30 days.

Similarly, in the present invention, the term "implantable by a minimally invasive approach" is used to mean that the device of the invention is sufficiently small to enable it to be implanted by a minimally invasive approach, and more particularly through a trocar, in particular a trocar having a diameter lying in the range 2 mm to 20 mm. Still more particularly, the device of the invention presents dimensions in terms of height and width that lie in the range 2 mm to 20 mm, and preferably in the range 5 mm to 10 mm.

A device of the invention can be used in minimally invasive surgery, in particular in robot-assisted surgery, and also in conventional surgery. Depending on the degree of miniaturization of the device, use thereof can be envisaged in various types of minimally invasive surgery, such as, for example:

- abdominal surgery;
- cardiothoracic surgery; and
- cervical surgery.

In a more advantageous embodiment, the device of the invention presents a mechanical structure that is simple and comprises, at least in part, and preferably completely, said bearing element, said blocking means, and said controlled tensioning means, forming a single integrally-formed mechanical part.

As mentioned above, the material constituting the elements making up the device of the invention is a

biocompatible material. Materials of this type can be metals, plastics, or composites, and are known to the person skilled in the art. Some are given by way of example in the detailed description below.

BRIEF DESCRIPTION OF THE DRAWINGS

Other characteristics and advantages of the present invention appear in the light of the following detailed description of embodiments given with reference to Figures 1 to 11, in which:

- Figures 1 to 4 show a first variant embodiment of a U-shaped suture device of the invention, with the device being shown in Figure 1 held stationary on an ancillary 1_2 prior to being put into place. In Figure 2, the device is shown at the moment the ancillary presses against the top portion of the device immediately prior to the threads being blocked together. In Figure 3, the device is shown while blocking is taking place. In Figure 4, the ancillary 1_2 has been removed and the suture device 1_1 is shown after blocking has taken place.
- Figures 5 to 7 show a second variant embodiment of a U-shaped suture device. In Figure 5, the device is shown held in place in its placing ancillary 1_2. Said ancillary is shown in face view in Figure 6 and in side view in Figure 7.
- In Figures 1-3 and 5-7, said ancillary is shown purely diagrammatically, and only the bottom portion thereof that co-operates with the device.
- Figures 8 to 10 show a second variant embodiment of a suture device of the invention comprising two plates interconnected by a conical spring which is shown in its initial position prior to blocking in Figure 8, then in its blocking position in Figure 9, and finally in the tensioning position of the device in Figure 10.
- Figure 11 shows a variant configuration for the notch 7_1 constituting the guide means in said bearing surface 4_1.

· In Figures 1 to 11, the suture device of the invention is shown diagrammatically so as to present its various component elements more clearly.

MORE DETAILED DESCRIPTION

In a first variant embodiment shown in Figures 1 to 7, the device of the invention is U-shaped and comprises:

· a bottom first branch 4_1 defining a said bearing surface and contact zone against said tissue;

· a top second branch 4_2 comprising said blocking zone and secured to or co-operating with said blocking means 2; and

· a junction element 4_3 between said first and second branches 4_1, 4_2 and made of a semirigid material presenting a said degree of elasticity. The junction element is straight or preferably curved so as to provide a hairpin junction between said two branches.

The entire device can be made of biocompatible materials that are metals, plastics, or composites, and in particular it can be made of 316L steel, of titanium, or of polypropylene.

In this embodiment, the space between the two branches of U has only two strands of thread passing therethrough, which strands can therefore be cut in this location, should that be necessary.

Said first tension value exerted by the device depends on a dimensional parameter, in particular on the section of the hairpin junction elements 4_3 and on the nature of the material used. It is preferably about 2 N for an application to surgery of the abdominal aorta using threads made of polypropylene 4.0.

Figures 1 to 4 are diagrams showing a suture device of the invention that is U-shaped in this first embodiment described below.

The top branch 4_2 defines a blocking zone having two jaws 2 that are initially open, i.e. spaced apart, serving to block the threads 3_1 and 3_2 by the threads rubbing against two adjacent and complementary surface 2_1

and 2_2 on respective ones of the two jaws 2 when said two complementary surfaces 2_1 and 2_2 close against each other with the threads thus being blocked between them.

The two jaws 2 are made of polypropylene, for example, and they are resiliently connected together, their two complementary surfaces 2_1 and 2_2 being initially held spaced apart by a spacer tab 2_3. In this case, the spacer tab 2_3 is secured to one of the jaws 2 at one end, while its other end carries a tooth 2_5 which co-operates with a notch 2_4 in the second jaw so that said two complementary surfaces 2_1 and 2_2 close against each other when said tooth 2_5 of the tab 2_3 is disengaged from the notch 2_4, thereby releasing the two jaws 2.

Said complementary structures 2_1 and 2_2 of the two jaws 2 are preferably of curved shape, forming on their surfaces paths towards the threads that are as long as possible so as to maximize the contact areas with the threads, so that the threads are blocked by friction than rather by clamping, so as to avoid damaging the threads.

The bottom branch 4_1 includes a central notch 7_1, itself covered on its underside by a pledget 7_2 made of Dacron® or Teflon® serving to hold the threads 3_1 and 3_2 apart at the orifices 6_1 and 6_2 where they leave the tissues for suturing together, the spacing between equal to 3 mm to 5 mm, for example, thereby preserving the integrity of said tissues and facilitating hemostasis.

The bottom branch 4_1, forming the zone of contact with the tissue, is connected to the top branch forming the blocking zone 4_2 by the resilient junction zone 4_3 and also by a first link element or link rod 5_1. Said link rod 5_1 has one of its ends secured to said bottom branch 4_1, and at its other end it carries a second tooth 5_3 which co-operates with a second notch 2_6 in the top branch 4_2, said second notch 2_6 being a lateral notch, i.e. a notch in one of the sides of the top branch 4_2.

The suture device 1_1 co-operates with an ancillary 1_2 on which it is held stationary. One of the jaws 2 (or

both jaws 2) of the top branch 4_2 is (or are) held relative to the ancillary 1_2, e.g. in a hollow housing 8_1 in which the jaw 2 is initially fitted and/or blocked.

So long as the link rod 5_1 is not engaged in said lateral second notch 2_6 of the top branch 4_2, and in the absence of any blocked thread, the top and bottom branches 4_1 and 4_2 are in a natural rest position in which they are spaced apart by a distance L + a.

When the link rod 5_1 is engaged in said lateral second notch 2_6 of the top branch, the device takes up a compressed state, and the distance between the two branches 4_1 and 4_2 is reduced, and corresponds to said initial distance L immediately before and during blocking.

The way in which the suture device of the invention is put into place and implemented is as follows:

1) The surgeon takes the suture device 1_1 secured to the ancillary 1_2 at the end of a rod of the ancillary 1_2, and places it close to the suture zone.

2) The surgeon perforates the pledget 7_2 in the notch 7_1 of the bottom branch 4_1 with the suture threads 3_1 and 3_2, passing through the pledget at 6_1 and 6_2. Passing two needles connected to the suture threads 3_1 and 3_2 through the pledget 7_2 is an act that is performed habitually by surgeons and presents no difficulty. Once the threads pass through the pledget 7_2, there is no longer any risk of the threads becoming tangled together. Furthermore, because the blocking mechanism is constituted by two jaws 2 that are held spaced apart by the spacer tabs 2_3, it is easy to insert the thread into the blocking mechanism, i.e. into the space defined by the two spaced-apart jaws 2 and said spacer tab 2_3.

3) Subsequently, the suture device can be lowered by the device sliding along the threads 3_1 and 3_2 passing through the pledget 7_2 and the space defined between the two jaws 2 and the spacer tab 2_3 (see Figure 1). The threads 3_1 and 3_2 are then under low tension and the

distance between the two branch or blocking zone 4_2 and the bottom branch or contact zone 4_1 corresponds to said initial distance L which is maintained by the connection rod 5_1.

4) On coming into contact with the tissues that are to be sutured together, the surgeon presses the device 1_1 against the tissues to be sutured by means of the placing instrument 1_2. Once the applied thrust force reaches a predetermined level having a said second value, and in particular a value of 10 N, the pusher element 8_2 of the ancillary provided for this purpose comes to press against the spacer tab 2_3, thereby causing the spacer tab 2_3 to bend in such a manner that its tooth or projection 2_5 moves out from the notch 2_4 (Figure 2), thereby triggering the two resiliently interconnected jaws 2 to move towards each other and press against each other so as to block the threads 3_1 and 3_2 between their complementary surfaces 2_1, 2_2 (Figure 3). At this stage, the threads 3_1 and 3_2 are blocked at a tension value that corresponds to the tension initially exerted by the surgeon on the threads while pushing the device against the tissues to be sutured together, and the distance between the contact zone of the bottom branch 4_1 and the blocking zone of the top branch 4_2 is L. Simultaneously, or immediately thereafter, the suture device firstly separates from the ancillary and secondly causes the link rod 5_1 between the bottom and top branches 4_1 and 4_2 to become disengaged so that the distance between the top and bottom branches 4_1 and 4_2 can become adjusted to a said final distance $L' = L \pm b$.

The resilient junction element 4_3 between the bottom branch 4_1 and the top branch 4_2 is designed in such a manner that when the distance between the bottom and top branches 4_1 and 4_2 is $L \pm b$ with $b < a$, the two branches exert a tension having said first predetermined tension value, in particular lying in the range 0.1 N to 10 N,

and more particularly having a value of 2 N, as explained above.

5) The threads can then be cut a few millimeters above said blocking zone 4_2, in particular 5 mm to 6 mm above, with the threads thus being blocked together and under tension at said selected first predetermined value as obtained as a function of the way in which the suture device is made and in particular the way in which the junction element 4_3 between the bottom and top branches 4_1 and 4_2 is made.

The threads 3_1 and 3_2 are thus blocked together automatically when the suture device comes into contact with the tissues that are to be sutured together and a bearing force is exerted on said device having a said second predetermined value, which in this case is 10 N. This value of 10 N corresponds to the force exerted by a vascular surgeon when pulling on the suture threads in order to tie a knot in a suture in the usual way. It should be observed that, prior to blocking, this initial 10 N bearing force is supported by the link rod 5_1, which keeps the bottom and top branches 4_1 and 4_2 spaced apart in spite of said bearing force. Once the spacer tab 2_3 has been disengaged and the two jaws 2 have been released, the movement towards each other of the resiliently-connected jaws 2 causes the threads to be blocked together and causes the distance between the bottom and top branches 4_1 and 4_2 to be come adjusted to a final distance ($L \pm b$ where $b < a$), at which distance said branches exert a tension on the blocked-together threads, which tension has said first predetermined value.

In addition, and advantageously, the ancillary 1_2 includes a spacer element 5_2 which prevents the bottom branch 4_1 with the device contact zone from moving too close to the top branch 4_2 with the blocking zones, i.e. approaching to a distance of less than L, so that the bottom branch 4_1 or contact zone 4_1 can be pressed against

the tissue for suturing without any risk of leading to anticipated disengagement, in particular by the link rod 5_1 twisting.

It should be observed that the space between the bottom branch 4_1 and the top branch 4_2 gives access for cutting the threads 3_1 and 3_2, should that be necessary in order to deactivate the suture device 1_1.

The automatic triggering of the mechanism for blocking the threads 3_1 and 3_2, followed by the tensioning of the blocked-together threads at a said first predetermined tension value, thus relieves the surgeon of any need to perform a whole set of acts, but without leading to any difficulty.

In Figures 5 to 7, there is shown a second embodiment of the first variant of a U-shaped suture device, which differs from the first variant as shown in Figures 1 to 4 as follows:

1) said second spacer element 2_3, for spacing apart the two jaws 2 constituting said blocking zone, no longer forms a part of the suture device 1_1 proper, but is integrated in the placing instrument 1_2; and

2) the top and bottom branches of the U-shape respectively defining said blocking zone 4_2 and said contact zone 4_1 are not initially interconnected by a link rod 5_1, but are held spaced apart by a said first spacer element 5_2, which forms an integral portion of the placing instrument 1_2.

As in the first variant of Figures 1 to 4, the suture device 1_1 of Figures 5 to 7 is held stationary on the placing instrument 1_2 via said blocking zone 2. More particularly, each of the jaws 2 is held in the spaced-apart position using the spacer bar 2_3 of the placing instrument 1_2, with the ends 2_{10} and 2_{11} of the bar being received in grooves 2_7 in each of the two jaws 2. The two jaws 2 in the spaced-apart position have their bottom faces coming to bear against the top faces at the top ends of each of said two first spacer elements 5_2 of the

ancillary, and the top faces of the two jaws 2 are held by a transverse bar 9_1 of the ancillary 1_2.

It should be observed that initially, prior to coming into contact with the tissues to be sutured together, the bottom branch 4_1 defining the contact zone of the device need not necessarily press against the bottom end of said spacer element 5_2 of the ancillary. The height of said spacer element 5_2 of the ancillary corresponds to said initial blocking distance L, such that said first spacer element 5_2 of the ancillary 1_2 makes it possible, when the contact zone 4_1 of the device is brought into contact with the tissues to be sutured together, and is then pressed thereagainst, to limit the bending of the intermediate junction element 4_3 of the device so as to maintain the distance between the blocking zone 4_2 and the contact zone 4_1 equal to said initial distance L. This initial distance L between the top blocking zone 4_2 and the bottom contact zone 4_1 corresponds to the mean value of the spacing (L ± b) that needs to be maintained between these two zones of the device in order to ensure that the suture threads have said first predetermined tension value after being blocked together.

At rest, prior to being put into place, the two jaws 2 are spaced apart by the spacer rod 2_3 of the ancillary, with the ends of the rod being received in the grooves 2_7 in each of the two jaws 2. The grooves 2_7 in the jaws 2 are symmetrical and designed to be of depth that varies from a deep end 2_8 towards a shallow end 2_9, such that:

· Initially, the ends 2_{10} and 2_{11} of the spacer rod 2_3 are received in the deep ends 2_8 of the grooves 2_7. In this position, the surgeon can perforate the fabric acting as the pledget 7_2 in the notch 7_1 with the suture threads, and can then cause the threads to pass through the space defined between the two jaws 2 and the spacer rod 2_3 of the ancillary. The assembly can then be put into contact with the tissues to be sutured without the

threads running the risk of escaping since they slide through the pledget 7_2 and in the space defined between the two jaws 2 and the spacer rod 2_3.

· Thereafter, on coming into contact with the tissues to be sutured together, pressure P is exerted in the direction NN' on the placing instrument 1_2, which pressure is transmitted to the spacer rod 2_3 which is in a position such that the axis NN' passes through the middle of the rod 2_3. As a result, the ends 2_{10} and 2_{11} of the spacer rod 2_3 slide along the grooves 2_7 from the deep ends 2_8 thereof towards their shallow ends 2_9, with the spacing between the two jaws 2 increasing.

· Then, once the thrust exerted on the ancillary reaches a bearing force having a said second predetermined value, e.g. of 10 N, the jaw spacer rod 2_3 escapes completely from the grooves 2_7. The two jaws 2, whose complementary surfaces 2_1 and 2_2 are connected together resiliently, then move towards each other, thereby blocking together the suture threads 3_1 and 3_2. At the instant blocking takes place, the contact zone 4_1 and the blocking zone 4_2 constituted by the two close-together jaws 2 are spaced apart by said initial distance L corresponding to the height of said first spacer element 5_2 of the ancillary 1_2.

The width of the two jaws 2 after they have moved together in this way is less than the distance ℓ between the top ends of said two first spacer elements 5_2 of the ancillary 1_2, so the ancillary can be withdrawn and separated from the device by being pulled upwards, the spacing between the contact zone 4_1 and the blocking zone 4_2 then no longer being controlled by said first spacer element 5_2 of the ancillary 1_2, whereupon it is said tension of said first predetermined value that is exerted by the top and bottom branches 4_1 and 4_2 of the device under the effect of the elasticity of the junction element 4_3 that acts on the blocked-together threads, and in particular a said first tension value of 2 N.

In a second variant embodiment of the invention as shown in Figures 8 to 10, the device is constituted by:

· a first plate 4_1 defining a said bearing surface for bearing against said tissue;

· a second plate 4_2 including said blocking zone; and

· said first and second plates 4_1 and 4_2 are connected together by a resilient junction element comprising a spring blade or wire.

More particularly, a device of the invention comprises:

· a said spring wire 4_3 defining a frustoconical envelope;

· said first plate 4_1 at the end of said spring that corresponds to the large base of said truncated cone formed by the spring;

· said second plate 4_2 at the end of said spring beside the small base of said truncated cone formed by said spring; and

· preferably, said spring 4_3 is suitable for being received in the empty central space thereof when it is compressed by moving said first and second plates towards each other.

It will be understood that in this embodiment, the suture threads pass inside the spring between said first and second plates.

The blocking zone 4_2 is preferably smaller in size than the contact element 4_1. In its compressed state, the spring occupies a minimum amount of space in the height direction. The dynamometer behavior is provided by the predefined stiffness of the spring.

This second variant embodiment with a frustoconical spring 4_3 differs from the U-shaped first embodiment of Figures 1 to 4 essentially by the fact that the intermediate junction element 4_3 is constituted by a said spring 4_3 of frustoconical envelope.

Otherwise, the blocking zone 4_2 is likewise constituted by two interconnected jaws. Said blocking

zone 4_2 is constituted by two resiliently-connected jaws 2 that are held spaced apart by a spacer rod 2_3 secured at one of its ends to one of the two jaws and co-operating at its opposite end with a notch 2_4 in the second jaw. The two jaws 2 are thus held spaced apart and can thus be held in place on a placing instrument 1_2. Thereafter, when a bearing force is exerted on the spacer rod 2_3, it bends and comes out of the notch 2_4 in the second jaw 2, such that the complementary surfaces 2_1 and 2_2 on the two jaws 2 can move towards each other and block the threads (Figure 9). Simultaneously, the connection rod 5_1 can become disengaged so that the distance between the first plate 4_1 and the second plate 4_2 is then controlled solely by the tension exerted by the connection spring 4_3. The connecting spring 4_3 is designed in such a manner that it exerts a tension having a said first value, in particular 2 N, when it goes away said initial distance L between the contact and blocking zones at the time of blocking in order to adopt a said final distance L ± b, as explained above.

In this second variant embodiment, the pressure exerted on the ancillary 1_2 thus causes the suture threads to be blocked together, after which it triggers tensioning of the suture threads once blocked together at a said first predetermined value.

In both variant embodiments shown in Figures 1 to 10, the suture device is such that:

· at rest, the distance between said contact zone 4_1 and said blocking zone 4_2 is equal to L + a;

· the distance between said contact zone 4_1 and said blocking zone 4_2 is equal to L when the device is in contact with the tissues to be sutured together and in a position ready for blocking, possibly with the device being held in place on its placing instrument (first variant); and

· the resilience of the various components of the device, and in particular of the intermediate junction

element 4_3 is designed so that when the distance between said contact zone 4_1 and said blocking zone 4_2 lies in the range L - b and L + b (where b < a), a force having said first value, and in particular a value of 2 N, is needed to keep the compressed device at said distance L ± b.

By way of illustration, values for L, a and b can be as follows:

L = 2 mm, a = 1 mm, b = 0.5 mm.

Thus, in these two variant embodiments, two situations can arise while the surgeon is putting the suture device into place:

1) First situation

When blocking is triggered, the tension being exerted by the surgeon on the suture threads is equal to T_1 where $T_1 < T_0$ (T_0 = the first predetermined tension value, e.g. 2 N), and the length of the strands of thread between said contact zone and said blocking zone is L.

In this first situation, when tensioning is triggered after blocking has taken place, the device is no longer held by the placing instrument 1_2 and seeks to expand since it is subjected only to the action of the tension T_1 in the threads, so the distance extending between said contact zone 4_1 and said blocking zone 4_2 as constituted by the two close-together jaws 2 will take on a value greater than L, i.e. L + b, where b < a. The tension exerted on the suture threads by the device is then equal to T_0 and the strands of thread prevent the device from expanding beyond the distance L + b, where b corresponds to the extent to which the threads lengthen under the effect of the difference in tension $T_0 - T_1$.

2) Second situation

When blocking is triggered, the tension exerted by the surgeon on the suture threads immediately prior to blocking is equal to $T_1 > T_0$ and the length of the strands

of thread between said contact zone and said blocking zone is L.

When, after blocking, tensioning of the threads by the device is triggered, the device will compress under the action of the tension T_1 in the threads, and the distance between said contact zone and said blocking zone will take on a value that is less than L, i.e. L - b, where b < a. The tension exerted by the device on the threads is thus equal to T_0 and the device prevents the threads from compressing beyond the distance L - b, where b corresponds to the shortening of the strands of thread under the effect of the difference in tension $T_1 - T_0$.

Figure 11 shows a variant embodiment of the guide means in said contact zone 1 having a said notch 7_1 that is in the form of a middle slot on the middle axis of said blocking zone together with two zones 7_3 that are disposed symmetrically about said middle slot, said two said symmetrical zones 7_3 comprising or defining retaining abutments for holding the two strands of thread 3_1 and 3_2 in a spaced-apart position where they pass through said zones, respectively. Said symmetrical zone 7_3 of the notch 7_1 are spaced apart so as to allow the two strands of thread 3_1 and 3_2 to be tensioned on the axes of said suture orifices 6_1, 6_2 so as to avoid applying any stresses to said suture orifices when exerting tension on the thread.

In the various embodiments, the suture device of the invention when applied to minimally invasive surgery can be put into place, for example, using a placing instrument 1_2 acting through a trocar having a diameter of 2 mm to 12 mm, said device having a said bearing surface and a said blocking zone which lie within a rectangular area of 2 mm^2 to 40 mm^2 and that are spaced apart by a maximum height of 10 mm.